REMARKS

STATUS OF CLAIMS

Claims 54, 57, 66, and 69 are objected to as dependent on rejected claims. All other claims are rejected.

THE AMENDMENTS

The amendments made to the independent claims were discussed with the examiner in the interview conducted October 12, 2004. The term "homogeneous," formerly used in the claims to describe the population of virus, has been replaced. Each claim now recites that "each virus" of the population "expresses on its surface the ligand for the polypeptide." This amendment is supported in the specification as originally filed, which teaches: "***Virus or phage compositions*** can include various amounts ***of the selected virus*** in combination with a pharmaceutically acceptable carrier and, in addition, if desired, may include other medicinal agents, pharmaceutical agents, carriers, adjuvants, diluents, etc." Specification at page 11, lines 1-3 (emphasis added). The claims already recited that the virus expresses the ligand on its surface.

The claims have also been amended to specify that the ligand specifically binds to the cell surface polypeptide. This is supported *inter alia* at page 7, last paragraph of the specification which teaches, "Specific binding between an (sic) receptor or channel and a ligand means that the ligand can be used to selectively remove the receptor or channel from a sample or to inhibit the receptor or channel's function and can readily by determined by radio immune (sic) assay (RA), bioassay, or enzyme-linked immunosorbant (ELISA) technology using an antibody, preferably monoclonal, specific for the ligand."

Each independent claim has also been amended to recite that the virus or

bacteriophage is recombinant. This is supported throughout the specification as a whole. See in particular, page 12, line 24 ("Monitoring receptor expression using recombinant bacteriophage with specific peptide ligands..."), at page 3, lines 19-20 ("...phage clones with specific interacting peptides from random peptide libraries have been isolated..."), at page 7, lines 6-8 ("The virus is modified to express the ligand on the surface of the virus, as by engineering the virus genome to encode a fusion protein for a coat protein and the ligand.")

These amendments are fully supported and do not add new matter to the application.

REJECTION OF CLAIMS 1, 5, 9, 17, AND 22 UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The enumerated claims are rejected for containing new matter: the recitation "homogenous population" allegedly has no clear support in the specification. Moreover, the recitation allegedly broadens the scope of the invention. These two allegations are respectfully traversed.

The claim term "homogeneous population" has been replaced with the recitation that "each virus" expresses the ligand on its surface. Support for this recitation is provided in the specification at page 11, lines 1-3 ("***Virus or phage compositions*** can include various amounts ***of the selected virus*** in combination with a pharmaceutically acceptable carrier and, in addition, if desired, may include other medicinal agents, pharmaceutical agents, carriers, adjuvants, diluents, etc."). As discussed during the interview, this recitation is adequately supported by the specification as filed.

Withdrawal of this rejection is requested in view of the amendment deleting the offending term.

REJECTION OF CLAIMS 1, 5, 9, 17, 22, 45-51, 53, 55-56, 58-63, and 70-75 UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The enumerated claims are rejected as being directed to generic methods that are not supported adequately by the species disclosed in the specification. This rejection is respectfully traversed.

The Manual of Patent Examining Procedure sets forth the standard for a rejection for lack of adequate written description (§2163):

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

The Patent Office has failed to meet its burden because it has failed to present any evidence at all why a person skilled in the art would not recognize that the disclosure described the invention defined by the claims.

The Patent Office alleges that the claims are generic and inadequately described in the following aspects:

- any virus
- any ligand.

However, it has not indicated why one of ordinary skill in the art would not be able to recognize that any virus or ligand could be used. Those of skill in the art are aware of many viruses and ligands. Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d

1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). The Patent Office has not presented any reasons why any of the known viruses and ligands could not be used in the claimed methods.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. In some cases one species adequately supports a genus. *See, e.g., Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326-27; *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteroid in DMSO held sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973). Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. M.P.E.P. § 2163. The Patent Office has not set forth why the species it acknowledges as being adequately described (*e.g.*, Mag 4.1 and Mag 4.2) are not representative of the entire claimed genus.

The Office Action has pointed to the working examples which describe the use of bacteriophage vectors expressing Mag proteins as fusion proteins in bacteriophage and the use of the bacteriophage for detecting NMDA receptors. However, the Patent Office has failed to assess the rest of the specification which indeed supports a generic scope for the claims. In the opening paragraph of the Detailed Description, the applicants describe the invention as being of the same scope as the claims:

> The present invention provides a method of detecting the presence of a polypeptide in a sample comprising contacting with the sample a detectable virus expressing on its surface a ligand for the polypeptide and detecting binding of the virus to the sample, thus detecting the presence of the polypeptide in the sample.

Page 6, lines 3-6. The disclosure is not limited to any specific virus or specific ligand. The generic scope of the invention is further supported in the disclosures of the individual components utilized in the claimed method. The virus as disclosed can be any virus:

> The virus utilized in the method can be a bacteriophage. For example the bacteriophage can be bacteriophage f1, M13, and other bacteriophages known in the art. ***Viruses can include any other desired virus, as will be recognized by those of skill in the art, such as adenovirus, etc.*** The phage or virus can be modified in any of various ways known in the art, such as to be rendered replication-deficient or to eliminate other viral genes, and methods of such modifications are standard in the art.

Page 7, lines 1-6 (emphasis added). The generic scope of the invention is further supported in the description of the ligand. There is no limit on the ligand which can be used:

> A ligand can be previously determined to specifically bind the selected protein by any known, standard means for determining such binding or, for example, as described herein. A ligand can include, for example, a peptide hormone, a toxin, a fragment from a large protein.

Page 8, lines 7-10. In sum, there is absolutely no indication that the applicants disclosed and described an invention that was any narrower than the claims.

Because the Patent Office has failed to meet its burden in making a *prima facie* case of inadequate written description, and because the specification describes the invention as being of the same scope as the claims, the rejection should be withdrawn.

REJECTION OF CLAIMS 1, 5, 9, 45-51, 53, 55-56 UNDER 35 U.S.C. §102(b)

Shatz (U.S. 5,270,120) is cited as anticipating claims 1, 5, 9, 45-51, 53, 55-56.

In order to find anticipation, each and every element set forth in the claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). Shatz does not teach each element and thus fails to

anticipate the claims.

The rejected claims recite:

- a detectable, recombinant virus expressing a ligand for the polypeptide on its surface which specifically binds to the polypeptide,
- a population of the detectable virus, each virus expressing on its surface the ligand for the polypeptide.

First, Shatz does not employ a population in which each virus expresses on its surface a ligand for a polypeptide. Shatz employs a random library of peptides of mixed identities. The present invention utilizes a ligand that is a member of a specific binding pair. This element alone distinguishes the pending claims from the teachings of Shatz.

Second, Shatz' invention does not employ a detectable, recombinant **virus expressing a ligand on its** surface. Shatz is cited as teaching the use of plasmids or phage vectors which express fusion products comprising a DNA binding protein. See column 6, lines 13-23. Shatz does not teach a virus with a ligand expressed on its surface.

Shatz fails to teach all elements of the claims. Therefore, Shatz does not anticipate the rejected claims.

REJECTION OF CLAIMS 1, 5, 9, 17, 22, 45-51, 53, 55-56, 58-63, 65, 67-68, and 70-75 UNDER 35 U.S.C. §103(a)

The enumerated claims are rejected as unpatentable over a combination of Shatz (U.S. 5,270,170) and Barbas, III (U.S. 6,242,568).

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. The rejection of the enumerated claims over Shatz and Barbas, III, fails to make a *prima facie* case because the prior art references fail to teach or suggest all the claim limitations.

Each of the rejected claims recites:

- a detectable, recombinant virus expressing a ligand for the polypeptide on its surface which specifically binds to the polypeptide,
- a population of the detectable virus, each virus expressing on its surface the ligand for the polypeptide.

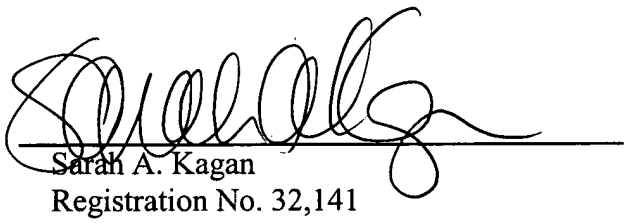
As detailed above, Shatz does not teach these elements of the claimed methods. Barbas, III, does not remedy these deficiencies. Barbas, III, is cited by the Patent Office merely to teach that fact that pVIII coat protein is expressed in multiple copies. This teaching clearly does not remedy the deficiency of Shatz in teaching an assay which uses a population in which each detectable, recombinant virus expresses a ligand on its surface, *i.e.,* the surface of a viral particle. Since neither reference teaches these elements the combination of references *per force* fails to teach these elements. On this basis the rejection fails to meet the Patent Office's own requirements for making a *prima facie* case. In view of this failure, the rejection should be withdrawn.

CONCLUSION

All rejections having been addressed, applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,

Dated: December 16, 2004

By: 

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